

## **REMARKS**

### **I. The Office Action**

The inventor's declaration was found to be defective for allegedly containing a non-initialed alteration. A replacement declaration is submitted herewith. The Office also objected to the abstract for not commencing on a separate sheet in accordance with 37 C.F.R. 1.52(b)(4). The objection is moot in view of the amendment to the abstract provided herein. Claims 28, 29, 31-38, 43, 44, 47, and 48 were rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Patent 4,792,447 ("the Uhr patent"). Claims 28-38, 43, 44, 47, and 48 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious in view of the Uhr patent taken with Bergsagel et al., *Blood*, 85, 436-447 (1995) ("the Bergsagel article"). The Office also rejected claims 28, 29, and 31-48 under 35 U.S.C. § 103(a) for allegedly being obvious in view of the Uhr patent taken with U.S. Patent Publication No. 2005/0255532 ("the Ruben publication"). Reconsideration of the rejections is respectfully requested.

### **II. Amendments to the Abstract and Claims**

The abstract has been submitted on a separate sheet in accordance with 37 C.F.R. § 1.52(b)(4). Claims 28, 33, 38, 40, 43, 47, and 48 have been amended to recite that the anti-LMA antibody or LMA ligand specifically binds LMA, as supported by the specification at, e.g., page 14, line 20, through page 15, line 3. No new matter has been added by way of these amendments.

### **III. The Section 102(b) Rejection Should Be Withdrawn.**

The Office rejected claims 28, 29, 31-38, 43, 44, 47, and 48 under Section 102(b) for allegedly being anticipated by the Uhr patent. The rejection is respectfully traversed.

The pending claims are directed, at least in part, to methods of using an anti-LMA antibody or LMA ligand that specifically binds LMA to treat a B-cell disorder (claim 28, 29, 31, and 32), kill or inhibit the growth of lymphoid cells (claims 33-37), or perform autologous hematopoietic cell transplantation (claim 38). The claims also are directed to an anti-LMA antibody conjugated to a cytotoxic moiety or biological modifier (claims 43 and

44) or labeled with a detectable moiety (claims 47 and 48), wherein the anti-LMA antibody specifically binds to LMA. "LMA," or "lambda myeloma antigen," is defined in the specification as a *free* lambda light chain, which is not associated with an intact immunoglobulin (see specification at, e.g., page 5, lines 5-8). The antibody or ligand of the pending claims specifically binds LMA, i.e., under particular conditions, the ligand or antibody binds LMA and does not bind to a significant degree other proteins or carbohydrates (see, e.g., page 14, line 29, through page 15, line 3, and Example 1). The Uhr patent does not teach or suggest an antibody or ligand that binds surface expressed *free* lambda light chain, much less an antibody or ligand that *specifically* binds LMA. Instead, the Uhr patent discloses antibodies directed against *intact* immunoglobulins. For example, at column four, first paragraph, the Uhr patent discloses that the described antibodies may bind a collective class of immunoglobulins by targeting the  $\lambda$  or  $\kappa$  light chain portion of an *intact* immunoglobulin. Intact immunoglobulins are expressed on both tumor and normal B-cells. LMA, on the other hand, is a target which is selective for tumor B-cells. The Office failed to demonstrate that the Uhr patent either explicitly or inherently discloses the claimed anti-LMA antibody or LMA ligand that specifically binds LMA, or methods of use as presently claimed. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (B.P.A.I. 1990). The Office has not met its burden in establishing that the Uhr patent discloses exactly what is claimed; therefore, the Section 102(b) rejection is improper and should be withdrawn. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 USPQ 773, 777 (Fed. Cir. 1985) ("[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed.").

#### **IV. The Section 103(a) Rejection Should Be Withdrawn.**

The Office rejected claims 28-48 under Section 103(a) for allegedly being obvious in view of the Uhr patent taken with the Bergsagel article and/or the Ruben publication. However, the subject matter of the pending claims is not obvious in view of the Uhr patent, the Bergsagel article, and the Ruben publication because the cited references fail to teach or suggest an anti-LMA antibody or a LMA ligand as recited in the pending claims. The Office asserted that the Uhr patent discusses antibodies against lambda light chain. As

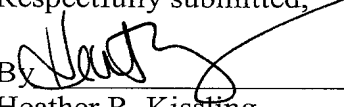
explained above, however, the Uhr patent discloses antibodies against intact immunoglobulin, not antibodies or ligands that specifically bind free lambda light chain expressed on the B-cell surface, as claimed. The secondary references do not cure the deficiencies of the Uhr patent in this regard. The Bergsagel article describes the identification of clonotypic B-cells in blood samples via analyzing immunoglobulin heavy chain rearrangements. Like the Uhr patent, the Bergsagel article discusses  $\kappa$  or  $\lambda$  light chains only in the context of *intact* immunoglobulin, which is expressed on normal *and* tumor cells. The Bergsagel article does not teach or suggest that *free* lambda light chain is present on the surface of multiple myeloma cells. The Rubin publication purportedly discloses therapeutic use of chimeric antibodies, labeled anti-tumor antibodies, and antibody conjugates. Neither secondary reference discloses or suggests an antibody or ligand that specifically binds *free* lambda light chain as claimed, nor do the references teach or suggest targeting surface-expressed *free* lambda light chain for the treatment of multiple myeloma. Thus, neither the Bergsagel article nor the Ruben publication, taken individually or in combination, cures the defect in the Uhr patent. Accordingly, the rejection under Section 103(a) has been overcome and should be withdrawn.

## V. Conclusion

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

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Respectfully submitted,

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